



653.1004

**UNITED STATES PATENT AND TRADEMARK OFFICE**

Re: Application of: Donald P. REITBERG  
Serial No.: 09/872,506  
Filed: June 1, 2001  
For: **Single-Patient Drug Trials Used With  
Accumulated Database: Risk Of Habituation**

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

August 22, 2002

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97, Applicant hereby makes of record the documents listed on the accompanying Form PTO-1449 for consideration by the Examiner in connection with the examination of the above-identified patent application.

This Information Disclosure Statement is filed under 37 C.F.R. § 1.97 (b), before the mailing date of a first Office Action on the merits.

It is respectfully requested that the references cited in the accompanying Form PTO-1449 be considered and made of record. If any of the publications listed thereon are missing, the Examiner is requested to contact the undersigned so that a copy can be promptly forwarded.

Applicant respectfully submits that the references cited in the accompanying Form PTO-1449 were cited in either the International Search Report or the Written Opinion from corresponding International Application No. PCT/US01/17700. Copies of the International Search Report, Written Opinion and cited references are enclosed for the Examiner's review.

**RECEIVED**

AUG 29 2002

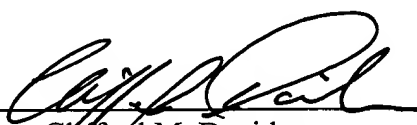
**GROUP 3600**

It is believed that no fee is due for this submission. If a fee is deemed to be due, the Commissioner for Patents is hereby authorized to charge said fee to Deposit Account No. 50-0552.

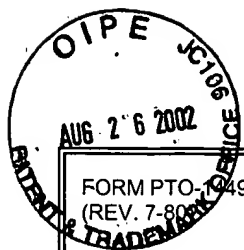
Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By

  
Clifford M. Davidson  
Reg. No. 32,728

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FORM PTO-1049  
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:  
653.1004

SERIAL NO.: 09/872,506

## LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S): Donald P. REITBERG

FILING DATE:  
June 1, 2001

GROUP:

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	6	0	2	9	1	3	8	02/22/00	Khorasani et al.	705	2	08/15/97
	AB	5	9	9	1	7	3	1	11/23/99	Colon et al.	705	3	02/01/99
	AC	5	5	9	4	6	3	7	01/14/97	Eisenberg et al.	395	202	05/26/93
	AD												
	AE												
	AF												
	AG												

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	AH	9	8	1	2	6	6	9	03/26/98	WO				
	AI	1	0	2	1	4	2	9	08/11/98	Japan				X
	AJ													
	AK													
	AL													

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AM	WEINHOLD, L.L. et al., "A Meta-analytic Model for Integrating Outcomes in Drug Research: Subjective Effects of Phenylpropanolamine Related to Abuse Potential," Journal of Clinical Research and Drug Development. 1994 Vol.8. pages 57-71.
	AN	SACHIDANANDAM, R. et al., "A map of human genome sequence variation containing 1.42 million single nucleotide polymorphisms," Nature. 15 February 2001, Vol. 409, pages 928-933.
	AO	LARSON, E.B. et al., "Randomized Clinical trials in Single Patients During a 2-Year Period," Journal of the American Medical Association. 08 December 1993, Vol. 270, No. 22, pages 2708-2712.
	AP	EVANS, W.E. et al., "Pharmacogenomics: Translating Functional Genomics into Rational Therapeutics," Science. 15 October 1999, Vol. 286, pages 487-491.
	AQ	Abstract of JP 1021429 (English)
	AR	

EXAMINER

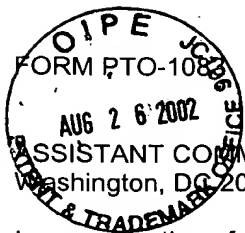
DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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9-04-02  
Docket No.: 653.1004  
Date: August 22, 2002

ASSISTANT COMMISSIONER FOR PATENTS  
Washington, DC 20231

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For: **Single-Patient Drug Trials Used With Accumulated Database: Risk Of Habituation**

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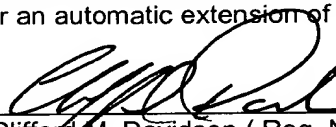
Transmitted herewith is a:

- ☐ Petition for extension under 37 C.F.R. 1.136 (in duplicate)
- ☒ Other: **-Information Disclosure Statement**  
**-PTO-1449 Form with cited references**  
**-Copy of International Search Report and Written Opinion from PCT/US01/17700**

- ☐ Check(s) in the amount of \$0.00 is/are attached to cover:
  - ☐ Filing fee for additional claims under 37 C.F.R. 1.16
  - ☐ Petition fee for extension under 37 C.F.R. 1.136
  - ☐ Other:

- ☒ The Assistant Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 50-0552.

- ☐ Any filing fee under 37 C.F.R. 1.16 for the presentation of additional claims which are not paid by check submitted herewith.
- ☒ Any patent application processing fees under 37 C.F.R. 1.17.
- ☐ Any petition fees for extension under 37 C.F.R. 1.136 which are not paid by check submitted herewith, and it is hereby requested that this be a petition for an automatic extension of time under 37 CFR 1.136.

  
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I hereby certify that this correspondence and/or documents referred to as attached therein and/or fee are being deposited with the United States Postal Service as "first class mail" in an envelope addressed to "Assistant Commissioner for Patents, Washington, D.C. 20231" on August 22, 2002

DAVIDSON, DAVIDSON & KAPPEL, LLC

BY: 

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